

EC DECLARATION of CONFORMITY

Regulation (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on medical devices

We, MOBILEX A/S
Registered place of business
Grønlandsvej 5
8660 Skanderborg
Denmark



SRN: DK-MF-000021885

Hereby declare under our sole responsibility as a legal manufacturer that the product specified on the product list below, meet the essential health and safety requirements and is in conformance with the provisions of the Regulation (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on medical devices.

The product specified on the product list below is "technical aid for the disabled", classified as Class I, medical device. The classification is based on the requirements of Rule 1 of annex VIII, of the Regulation (EU) 2017/745.

Intended purpose:

intended to be used only as a standing & walking assistant during walk reeducation by patients that because of invalidity are unable to stand & walk independently and who require additional stable support during walking.

The CE marking has been affixed on the product according to Annex V of the Regulation (EU) 2017/745.

PRODUCT LIST

DynaWalk:

REF / item no.	313001	313002
UDI-DI	5740001437058	5740001437065
BASIC-UDI-DI	57400014DYNAWALKRY	

ACCESSORIES LIST

Item nr.	Accessories item nr.
313001+02	NO

Harmonized norms used during conformity estimation:

PN-EN ISO 11199:2005, EN ISO 14971:2012, EN 1041:2009

Skanderborg, 2022-04-26, Thomas N. Christensen, Managing Director

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